CLERK'S OFFICE U.S. DISTRICT COURT AT ABINGDON, VA FILED

UNITED STATES DISTRICT COURT WESTERN DISTRICT OF VIRGINIA ABINGDON

JUN 11 2021

JULIA C. DUDYEY, CLERK

UNITED STATES OF AMERICA

;

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Criminal No. 1:21 CR00034-00

JAMES CHADWICK BROOKS

Violations: 21 U.S.C. §§ 331(d), 355, and

333(a)(2)

and

:

CCB NUTRITION, LLC

v.

:

INFORMATION

INTRODUCTION

The United States Attorney charges that:

- 1. At all times relevant to this information, James Chadwick Brooks ("Brooks") was a Georgia resident and United States citizen.
- 2. CCB Nutrition, LLC ("CCB Nutrition") is a Georgia company incorporated by Brooks on or about March 8, 2016, with its principal place of business in Georgia. Brooks incorporated CCB Nutrition for the purpose of manufacturing and distributing bodybuilding supplements and dietary supplements throughout the United States.
 - 3. Brooks and CCB Nutrition are collectively referred to as the Defendants.
- 4. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulates the manufacture and distribution of all food (including dietary supplements) and drugs shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 301, et seq. ("FDCA"). The requirements of the FDCA, in part, are meant to ensure that food and drugs sold for human use are safe and bear labeling that contains accurate and adequate information.

Information United States v. Brooks

- 5. The FDCA defines a "drug" in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any article used as a component of either. 21 U.S.C. § 321(g). Whether an article is a drug is determined by its intended use, which is defined as "the objective intent of persons legally responsible for the labeling of drugs." The intent is determined by "such person's expressions or may be shown by the circumstances surrounding the distribution of the article." Such intent may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. 21 C.F.R. § 201.128.
- 6. A drug is misbranded under the FDCA if its label is false or misleading in any particular, fails to bear adequate direction for use, or fails to bear adequate warnings. 21 U.S.C. § 352(a)(1); 21 U.S.C. § 352(f).
- 7. Some drugs are "new drugs," which are defined as any drugs the composition of which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. 21 U.S.C. § 321(p). It is a prohibited act for any person to introduce or deliver for introduction or to cause the introduction or delivery for introduction into interstate commerce any new drug unless it has been the subject of a new drug application approved by FDA. 21 U.S.C. § 331(d), 355(a). Such introduction or delivery for introduction into interstate commerce is a felony violation when it is done with the intent to defraud and mislead. 21 U.S.C. § 333(a)(2). Unlike drugs, dietary supplements are not subject to the requirement that manufacturers and distributors obtain FDA approval before introducing such products into interstate commerce.

- 8. Anabolic steroids, also known as anabolic androgenic steroids, are a class of hormones that regulates the development and maintenance of male characteristics. They include both natural androgens, like testosterone, and synthetic androgens, which mimic testosterone's effects. They are routinely marketed to promote muscle growth, enhance athletic, or other physical performance, and improve physical appearance. Anabolic steroids may have dangerous effects on users, including increasing the risk of liver damage, coronary artery disease, strokes, and heart attacks. Anabolic steroids are Schedule III substances under the Controlled Substances Act. 21 U.S.C. § 812 (a); 21 C.F.R. 1308.13; 21 C.F.R. 1308.13. The FDA has further warned of the abuse of anabolic steroids, and requires specific labeling on all prescription testosterone products.
- 9. On March 8, 2016, Brooks established CCB Nutrition. During the operation of this business, Brooks worked with other companies to create, bottle, and label drug products containing workout supplement products; marketed these products to those in the body-building and fitness community to increase muscle mass or otherwise affect the structure or function of the body; and distributed these products in interstate commerce from Georgia and Texas to other states throughout the United States.
- 10. Beginning on or about May 2016 and continuing to October 2019, Defendants introduced misbranded drugs and unapproved new drugs into interstate commerce. In particular, Defendants introduced and delivered for introduction, and caused the introduction or delivery for introduction into interstate commerce, the following drugs and new drugs on or about the dates indicated below:

Approximate Date(s)	Product Details	Active Ingredient(s)
6/2/2016 7/29/2016	Fitness Factory – 11oxo 90ct	Adronosterone
6/2/2016 7/29/2016	Fitness Factory – Androsterone 90ct	Androsterone
7/28/2016 9/1/2016	JVICE VPO Brute	Trestolone(10mg) Max Lmg(25mg) Dymethazine (10mg)
6/2/2016	Fitness Factory Stanodrol 60c	Epiandrosterone (300mg)
7/29/2016	Geared Up Nutrition Torque 60ct	Methylstenbolone (10mg) Dymethazine (10mg)
10/26/2016	JVICE VPO Propvne 60ml	Methylstenbolone (10mg)
10/2/2019	Forbidden Labz Conquer-Arimistane	Arimistane

- 11. All of the above products were intended to affect the structure or any function of the body, rendering them drugs under 21 U.S.C. § 321(g)(1). The above products also were misbranded drugs because they were manufactured in an unregistered facility in Texas. 21 U.S.C. 331(a); 21 U.S.C. 352(o). Brooks received some of the above misbranded products in interstate commerce after they were manufactured in Texas. 21 U.S.C. 331(c).
- 12. The above products also were new drugs that required FDA approval before they could be lawfully distributed in interstate commerce. 21 U.S.C. 331(d). These products further failed to bear labeling with adequate directions for use, as is required for new drugs. 21 CFR 201.100.
- 13. Brooks knowingly took steps to mislead and defraud the Government and consumers in the sale of the above products. Brooks knew certain ingredients in the above products were subject to scrutiny by government law enforcement agencies, including the FDA and Drug Enforcement Agency. To help hide his involvement, Brooks hired an unregistered contract manufacturer to manufacture many of the above products and import the necessary

materials to do so. Brooks knowingly failed to obtain regulatory approval for all of the above products.

14. During the period of 2016 to 2020, the Defendants caused the distribution of not less than \$350,000 worth of the above drugs.

COUNT ONE

The United States Attorney charges that:

- 15. The Introduction is re-alleged and incorporated by reference.
- 16. From on or about May 2016 and continuing to October 2019, JAMES CHADWICK BROOKS and CCB NUTRITION, LLC, with the intent to defraud and mislead, introduced and delivered for introduction into interstate commerce quantities of misbranded drugs and new drugs, which FDA had not approved for distribution in the United States.
- 17. JAMES CHADWICK BROOKS used his business entity, CCB NUTRITION, LLC, to cause the interstate distribution of drugs and unapproved new drugs throughout the United States and elsewhere.
 - 18. All in violation of 21 U.S.C. §§ 331(d), 355, and 333(a)(2).

NOTICE OF FORFEITURE

- 19. Upon conviction of the offense alleged in this Information, JAMES CHADWICK BROOKS and CCB NUTRITION, LLC, shall forfeit to the United States unapproved new drugs, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461, that were shipped to various locations in the United States.
- 20. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of \$350,000 pursuant to 21 U.S.C. § 853(p).

DATED: June 10, 2021

DANIEL P. BUBAR

Acting United States Attorney

By:

Randy Ramseyer

Randy Ramseyer

Assistant United States Attorney

GUSTAV W. EYLER

Director

Consumer Protection Branch

U.S. Department of Justice

By:

Speare I. Hodges
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